



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	P-LJ-3578	8259
41552	7590	06/13/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			SANG, HONG	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Hong Sang

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RE: Reed

1. Applicant's response filed on 4/20/2006 is acknowledged.
2. Claims 11-14, 16, 20-27, 32-34, 36-37, 44 and 50-66 are pending and under examination.

Response to Arguments

3. The rejection of claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 under 35 U.S.C. 102(b) as being anticipated by Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) is maintained.

The response states that "BBE patients" are not separate patients to which cancer patients are compared. The 10-year overall survival (OS) and distant disease free survival (DDFS) for breast cancer patients with overexpression of BAG-I in the nuclear component of BBE was 77% and 81%, respectively, compared to 54% and 40% for BBE with low levels of BAG-I. The 10-year OS and DDFS for patients with overexpression of cytoplasmic BAG-I in IC specimens was 75% and 70%, respectively, compared to 62% and 35% for tumors with low cytoplasmic BAG-I levels. It was found that 93% of specimens containing IC had overexpression of BAG-I. Of the 5 cases of pure DCIS, overexpression of BAG-I was found in 80% of the specimens (40% having nuclear and cytoplasmic and 40% having nuclear only). Of the 53 cases having areas of BBE, overexpression of BAG-I was found in 47% of specimens. The Turner et al. reference concludes, "that the subcellular location of BAG-1 may have prognostic

Art Unit: 1643

importance with respect to survival of breast cancer patients". Thus, Turner et al. provides no teaching of methods for prognosis of breast cancer, predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, or determining the proper course of treatment for a patient suffering from breast cancer in a patient during stage I or stage II of breast cancer, as claimed. At best, Turner et al. suggests that the subcellular location of BAG-I may have prognostic importance but provides no teaching that the level of BAG-I protein expression in a sample is prognostic for stage I or stage II of breast cancer. The response further states that Turner et al. describe a higher percentage of overexpression of BAG-I in cancerous IC (93%) and in DCIS (80%) than in benign BBE (47%). Therefore, based on the description in Turner et al., as a tissue becomes cancerous or becomes a more aggressive form of cancer, overexpression of BAG-I increases. Furthermore, Turner et al. indicates that, in BBE, overexpression of BAG-I was found to be in a higher proportion in the nucleus alone (30%) than in the cytoplasm and nucleus (13%) or cytoplasm alone (4%). In IC, overexpression of BAG-I was found to in a higher proportion in the cytoplasm alone (89%) than in the cytoplasm and nucleus (22%) or nucleus alone (4%). From these observations, Turner et al. concludes that the subcellular location of BAG-I overexpression may be prognostic but provides no teaching that overexpression of BAG-I would be prognostic for stage I or stage II breast cancer. Absent such a teaching, Applicants respectfully submit that Turner et al. cannot anticipate the claimed methods.

Applicants' arguments have been carefully considered but are not found persuasive. Turner et al. teach determining BAG-1 expression in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast by immunohistochemistry using a monoclonal antibody. Because the instant specification teaches stage I of breast cancer requires no lymph node involvement, and stage II of breast cancer involves either no lymph node involvement and a large primary tumor or initial lymph node involvement and a small primary tumor (see specification, page 25, lines 17-22), at least stage II breast cancer recited in the claims is invasive cancer. Moreover, DCIS in Turner's reference is considered as stage I breast cancer. Therefore, Turner teaches determining BAG-1 in stage I and stage II breast cancer. Turner et al. teach that the patients had a median follow-up for 13 years. Turner et al. teach that the 10-year overall survival (OS) and distant disease free survival (DDFS) for breast cancer patients with overexpression of BAG-1 in IC specimens was 75% and 70%, respectively, compared to 62% and 35% for tumors with low cytoplasmic BAG-1 levels. Therefore, Turner et al. teach the method of correlating the disease-free or overall survival of an individual having a breast cancer tumor with the overexpression of BAG-1 protein, wherein the breast cancer includes at least stage II breast cancer. The instant specification teaches that the reference level may be determined by measuring level of expression of BAG in non-tumorous cancer cells from the same tissue as the tissue of cancer cells to be tested (see specification page 18, lines 4-13), the reference level may also be determined by comparison of BAG expression levels in populations of patients having the same cancer (see specification page 18, lines 24-26), and the

Art Unit: 1643

reference level can also represent the level of BAG protein in one or more compartments of the cell (see specification page 21, lines 3-5). Turner et al. teach that breast cancer patients having overexpression of BAG-1 in either nucleus or cytoplasm have higher rate of 10-year survival and distant disease free survival compared to patients having low expression of nuclear or cytoplasmic BAG-1. Therefore, Turner teaches all the limitations of the claims.

4. The rejection of claims 11-14, 16, 21-22, 24-27, 32-34, 36-37, 44 and 50-61 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sano et al. (US patent NO. 5665539) is maintained.

The response states that Turner et al. does not teach or suggest the claimed methods for the same reasons set forth above, and Sano et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sano et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Sano.

5. The rejection of claims 11, 13-14, 16, 20-22, 24-27, 32, 34, 36-37, 44 and 50-66 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer

Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sauter et al. (British Journal of Cancer, 1997, 76(4): 494-501) is maintained.

The response states that Turner et al. does not teach or suggest the claimed methods for the same reasons set forth above, and Sauter et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sauter et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13-14, 16, 21-22, 24-27, 32, 34, 36-37, 44 and 50-61 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Sauter.

6. The rejection of claims 11, 13-14, 16, 21-27, 32, 34, 36-37, 44 and 50-61 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Takayama et al. (Cancer Res. 1998, 58: 3116-3131, IDS) is maintained.

The response states that Turner et al. does not teach or suggest the claimed methods for the same reasons set forth above, and Takayama et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Takayama et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13-14, 16, 21-22,

24-27, 32, 34, 36-37, 44 and 50-61 has been set forth above (see paragraph 3).

Therefore, the claimed methods are obvious in view of the teachings of Turner and Takayama.

Conclusion

7. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Hong Sang
Art Unit: 1643
May 31, 2006